

REMARKS

Claims 2, 3, 5, 7, 8, 10, 13, 16-17, 20, 22-23, 25-35, 37-45 are pending in the present application. Claims 9 and 21 are cancelled without prejudice or disclaimer of the subject matter recited therein.

Claims 13, 37-40, and 45 are rejected under 35 U.S.C. 112, second paragraph as being indefinite. Claim 13 is amended to reflect a method of detecting the presence of an analyte. Claims 13 and 45 are further amended to recite that "changes" in the detection element are "optical" changes. Support for the amendments is found in the specification as filed and specifically at Example 2, pages 24-25. No new matter is added by virtue of the amendments to the claims. Claims 37-40 depend from amended claim 13.

Reconsideration of the rejection, in light of the amendments, leading to withdrawal of the rejection and allowance of the claims is respectfully requested.

Claims 2-3, 7-10, 13, and 16-17, 20-23, 26, 27 and 29-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada (US Pat. 5,399,316) in view of Hodges et al. (US Pat. 5,942,102) and Zimmer et al. (US Pat. 5,814,522). It is submitted that the resulting combination or modification proffered by the rejection fails to show or suggest a device as recited in the pending amended claims.

Claims 41, 43 and 45 are each amended to recite that the carrier is inert and to require an inert cover. Moreover, the claims are amended to recite that the capillary channel is formed by the inert carrier, the detection element, and the inert cover, the cover and the detection element being mounted end to end in such a way that the capillary channel extends without interruption from the sample application opening to the vent opening. Support for the amendment is found in the specification at page 20 lines 26-31, original claim 8, and Figures 2-5. No new matter is added by the virtue of the amendments.

Regarding independent claims 41, 43 and 45, it is submitted that Yamada fails to disclose or suggest a test element comprising a capillary channel defined by an inert cover, an inert carrier, and a detection element as recited in the present claims.

First, the rejection's proffer that the reaction region (21) of Yamada and the reagents therein is considered to read on the detection element of the invention is traversed in light of the amendments to the claims and for at least the following reasons:

1. The detection element of the present claims has a surface that faces an inert carrier. The reaction region (21) of Yamada is a region, not an individual component and as such, lacks a surface facing an inert carrier. At Column 5 lines 7-9, Yamada teaches that the reaction region (21) is just that, a region, surrounded by the base member (11), the spacers (12 and 13) and the cover (17).
2. The detection element of the present claims is mounted end to end with the cover. Yamada discloses a cover (17) that extends from the notched portion (15) to the recess (12). The ends of the cover (17) define the ends of the main body (20). There is no additional element, let alone a detection element lying end to end with its cover (17) in such a way that the capillary channel extends without interruption from the sample application opening to the vent opening.
3. The inert carrier, the detection element and the inert cover form the capillary channel of the present claims. Yamada discloses a groove (14) surrounded by the cover (17), the spacers (12, 13), and the base (11). Yamada fails to disclose or suggest an additional element, let alone a detection element end to end with the cover (17) that cooperates with the base member (11) and spacers (12, 13) to define the groove (14).
4. The pending claims recite that the detection element is formed to permit liquid penetration therein. Yamada teaches that the groove 14 operates by a capillary phenomenon. (Column 5 lines 13-18). When the width of the reaction region (21) is excessively large, the dispersion rate becomes nonuniform, and the cleaning efficiency may be degraded. As such, Yamada teaches away from the individual members (11, 12, 13, 17) forming the groove (14) permitting liquid penetration therein. As such, the members (11, 12, 13, 17) teach away from the recited detection element of the present claims.

In light of the above, it is submitted that neither the reaction region (21) nor the elements (11, 12, 13, 17) that surround region (21) of Yamada teach or suggest a detection element as recited by the pending amended claims.

Second, the rejection's proffer that the instant claims fail to exclude the base member (11), the spacers (12 and 13) or the cover (17) as possible sites for placement of the reagents is traversed in light of the amendments to the claims and at least for the following reasons:

1. The pending amended claims require that both the cover and the carrier be inert.
2. The pending claims require that the detection element contain a reagent. As discussed above, spacers (12, 13) are set such that a sample solution spreads in the reaction region (21) by a capillary phenomenon. Spacers (12, 13) accordingly are not formed for liquid penetration and would be excluded as a possible element for containing a reagent.

In light of the above, it is submitted that the base member (11), the spacers (12 and 13) and the cover (17) of Yamada are excluded as possible sites for containing the reagent.

Accordingly, Yamada fails to disclose or suggest a test element comprising a detection element as recited by the pending claims. It is further submitted that the existence of a single cover and a single base member that cooperate to define ends of the body member teach away from the addition of a detection element lying end to end with the cover.

It is submitted that the secondary references when taken either alone or in combination with one another, fail to cure the inadequacies of Yamada. First, Hodges et al. is devoid of description or suggestion of a test element having a detection element formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element including a second surface facing the first surface, as required by each of the independent claims. In that regard, the Examiner's attention is directed to Figures 10 and 11 of Hodges.

At most, Hodges teaches that the aperture 8 is defined by opposing palladium coatings 2, 6 and by cylinder side wall 10. As such, Hodges et al. lacks a test element comprising a detection element as recited by the present claims, and fails to cure the inadequacies of Yamada.

Zimmer et al. also is devoid of description or suggestion of a test element having a detection element formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element including a second surface facing the first surface, as required by each of the independent claims. Specifically, Zimmer et al. fails to teach or suggest a channel that is formed at least partially by a first surface of the carrier and a second surface of the detection element, let alone wherein that detection element is formed to permit liquid penetration therein and including at least one reagent contained therein.

The capillary gap 11 of Zimmer in Figures 3 and 4 is simply not defined in part by its areas 6, 7 containing reagent. In that regard, the Examiner's attention is directed to Figure 3 of Zimmer, where the capillary gap is defined by the fleece 1, covering foil 9, and spacer 10 and Figure 4 where the capillary gap is defined by the fleece 1, support foil 8 and the spacer 10. In each of the Figures 3, 4, the area 6 (Figure 3) and areas 6,7 (Figure 4) fail to form a portion of the capillary gap 11. As such, Zimmer et al. fail to cure the inadequacies of Yamada and Hodges et al.

In light of the above, it is submitted that Yamada, Hodges et al., and Zimmer et al. when taken as a whole, fail either alone or in combination to disclose or suggest a test element comprising, "an inert cover, an inert carrier having a first surface, a detection element being formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element including a second surface facing the first surface, and a capillary channel including a sample opening and a vent opening and extends in a direction of capillary transport from the sample opening to at least an edge of the detection element that is nearest to the vent opening, wherein the capillary channel is formed by the inert carrier, the detection element, and the inert cover, the cover and the detection element being mounted end to end in such a way that the capillary channel extends without interruption from the sample application opening to the vent opening and a notch is positioned at an edge of the test

element forming the sample opening so that a surface opposite to the notch is exposed.”, as recited in amended claim 41. Claims 2-3, 5, 7-8, 10, 13, 16-17, 20, 22-23 and 42 depend from claim 41.

It is further submitted that Yamada, Hodges et al., and Zimmer et al. when taken as a whole, fail either alone or in combination to disclose or suggest a test element comprising, “an inert cover, an inert carrier having a first surface, and a detection element being formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element having a second surface facing the first surface, the channel including a sample opening and a vent opening and extends in a direction of capillary transport from the sample opening to at least an edge of the detection element that is nearest to the vent opening, wherein the capillary channel is formed by the inert carrier, the detection element, and the inert cover, the cover and the detection element being mounted end to end in such a way that the capillary channel extends without interruption from the sample application opening to the vent opening and a notch is positioned at an edge of the test element forming the sample opening so that one side of the edge is discontinuous,” as recited by amended claim 43. Claims 25-35 and 44 depend from claim 43.

Finally, Yamada, Hodges et al., and Zimmer et al. when taken as a whole, fail either alone or in combination to disclose or suggest a method for determining an analyte in a liquid sample, the method comprising the steps of “providing an analytical test element including an inert cover, an inert carrier having a first surface, a detection element being formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element including a second surface facing the first surface, and a capillary channel including a sample opening and a vent opening and extends in a direction of capillary transport from the sample opening to at least an edge of the detection element that is nearest to the vent opening, wherein the capillary channel is formed by the inert carrier, the detection element, and the inert cover, the cover and the detection element being mounted end to end in such a way that the capillary channel extends without interruption from the sample application opening to the vent opening and a notch is positioned at an edge of the test element forming the sample opening so that a surface opposite to the notch is exposed, contacting the test element with the liquid sample at the notch so that the liquid

sample is transported by capillary forces into the channel, and observing the liquid sample in the detection element to determine whether optical changes in the detection element exist following contact with the liquid sample, wherein the changes relate to a presence of the analyte in the liquid sample," as recited in amended claim 45. Claims 37-40 depend from claim 45.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Entry of the amendments, reconsideration of the rejections of the claims, and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 5 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada (US Pat 5,399,316) in view of in view of Hodges et al. (US Pat. 5,942,102) and Zimmer et al. (US Pat. 5,814,522) as applied to claims 2-3, 7-10, 13, 15-27, and 29-40 above, and further in view of Heller et al. (US Pat. 6,238,624).

Yamada, Hodges et al., and Zimmer et al. have been discussed above with reference to claims 41 and 43. Heller et al. disclose a self-addressable, self-assembling microelectronic device designed and fabricated to actively carry out and control multi-step and multiplex molecular biological reactions in microscopic formats. See, the abstract. Heller et al. fail to cure the inadequacies of Yamada, Hodges et al., and Zimmer et al., in relation to claims 41 and 43. Claim 5 depends from claim 41 and claim 28 depends from claim 43.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 2-3, 5, 7-10, 13, 16, 17, 20-23, 25-35, and 37-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,592,815 (hereinafter '815) to Zimmer. The rejection is respectfully traversed. It is respectfully submitted that the two sets of claims do not read on each other. However, if the rejection is maintained, a terminal disclaimer will be submitted upon receipt of a Notice of Allowance for this matter.

As discussed above, each of the pending independent claims recites a test element having an inert cover, an inert carrier and a detection element, wherein a capillary channel is formed by the inert carrier, the detection element, and the inert cover, the cover and the detection element being mounted end to end. Neither independent claim 1 nor claim 15 of the '815 patent recites this specific arrangement.

The claims as submitted herein are believed to be in condition for allowance, and allowance of the application is respectfully requested. In addition, it is requested that this paper be considered a request for an extension of time and that all fees due be charged to Deposit Account Number 50-0877 with reference to (RDID 0044 US).

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Respectfully submitted,



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